FEB 2 9 2012

510(k) Summary

Apex Revision Knee ™ System 29 September, 2011

Submitter	OMNIlife science, Inc. 50 O'Connell Way Suite #10 E. Taunton MA 02718	**Contact**	Radhika Pondicherry Regulatory Affairs 774-226-1852 (508) 822-6030 (fax)

Preparation Date	29 September, 2011
Device Nam	
Trade Name	Apex Revision Knee System
Common/Classification Name	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis.
Regulatory Class	Class II per 21 CFR §888.3560, 21 CFR §888.3565
Product Code	JWH, MBH
Legally Marketed Predicate Device(s)	• K060192- Apex Knee™ System- cleared 15Jul2006 • K102578- Apex PS Knee™ System, cleared 25May2011 • K952830- Darwin Knee System (TC3) cleared 18Jan1996

Device Description

The Apex Revision Knee System includes the Revision Femoral Component, PS-R Insert, Retaining bolts, Femoral Augments and Femoral Stems. The Revision system is compatible with the previously cleared Modular Tibial Baseplates (K101994) and Patella component (K060192). The PS-R Insert has one level of medio-lateral constraint. The Revision Femoral component incorporates a proportionally sized box that is higher than the Apex PS Knee design (K102578). The Revision Femoral Component has the same bone cuts as the Apex CR Knee System and the Apex PS Knee System (K060192 and K102578). Size ranges, high flex and all other key design features of the Apex CR Knee System (K060192) have been retained in the Apex Revision Knee System. The Femoral Augments and Femoral Stems are available for use with the Revision Femoral Component.

Indications for Use

The Apex Knee™ System is intended for use as a primary or revision total knee replacement. This prosthesis may be used for the following conditions, as appropriate:

- Non-inflammatory degenerative joint disease, including osteoarthritis and avascular necrosis;
- Rheumatoid arthritis;
- Correction of functional deformity;
- Revision procedures where other treatments or devices have failed;

The porous coated femoral component may be used cemented or uncemented (biological fixation). The porous coated tibial baseplate

component may be used uncemented (biological fixation). All other femoral, tibial baseplate and patellar components are indicated for cemented use only.
The Apex Knee™ Modular Tibia System Tibial Augments are intended to be bolted to the Tibia Baseplate and cemented to the prepared tibia. The Apex Revision Knee System augments are intended to be bolted to the femoral component and cemented to the prepared femur.

Predicate Device Comparison

The Apex Revision Knee System is manufactured, packaged, and sterilized using equivalent materials and processes as the predicates. The subject device(s) is also substantially equivalent to its predicate(s) based on comparison of design features, intended use, and indications for use. The safety and effectiveness of the Revision Knee is adequately supported by the substantial equivalence information, materials information, and analysis data provided within this Premarket Notification.

Non-Clinical Test Summary

Revision Femur Stem Location Analysis

Apex PS Knee Revision Femur Flexion Range of Motion

- ASTM F2083-08- Standard Specification for Total Knee Prosthesis
- FDA -Class II Special Controls Guidance Document: Knee Joint Patellofemorotibial and Femorotibial Metal/Polymer Porous-Coated Uncemented Prostheses: Guidance for Industry and FDA

Apex Revision Knee Lift-off (Jump Height) Comparison

Tibio-Femoral Constraint of the Apex PS Knee, Revision femur and PS-R Insert

- ASTM F2083-08- Standard Specification for Total Knee Prosthesis
- ASTM F1223-03- Standard Test Method for Determination of Total Knee Replacement Constraint

Contact Area of the Apex PS Revision Knee

- ASTM F2083-08- Standard Specification for Total Knee Prosthesis
- FDA -Class II Special Controls Guidance Document: Knee Joint Patellofemorotibial and Femorotibial Metal/Polymer Porous-Coated Uncemented Prostheses: Guidance for Industry and FDA

Revision Knee Insert post Strength

- FDA Class II Special Controls Guidance Document: Knee Joint Patellofemorotibial and Femorotibial Metal/Polymer Porous-Coated Uncemented Prostheses; Guidance for Industry and FDA, issued on January 16, 2003

Apex Knee Stem Testing

Revision Knee Femur Augment Testing

Apex PS Revision Knee Patello-Femoral Contact Area and Stability

- ASTM F2083-08 Standard Specification for Total Knee Prosthesis
- FDA Class II Special Controls Guidance Document: Knee Joint Patellofemorotibial and Femorotibial Metal/Polymer Porous-Coated Uncemented Prostheses; Guidance for Industry and FDA, issued on January 16, 2003

Apex PS Revision Knee Wear Review

- ISO 14243-3- Implants for surgery -- Wear of total knee-joint prostheses --

Part 3: Loading and displacement parameters for wear-testing machines with displacement control and corresponding environmental conditions for test.

- ISO 14243-2- Implants for surgery -- Wear of total knee-joint prostheses -- Part 2: Methods of measurement
- ASTM F1877- Standard Practice for Characterization of Particles

All samples tested met the acceptance criteria.

Clinical Test Summary

No clinical studies were performed.

Conclusions

The Apex Revision Knee System is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

FEB 29 2012

OMNIlife science, Inc.
% Ms. Christine Nassif
Director, Regulatory Affairs
50 O'Connell Way, Suite 10
East Taunton, Massachusetts 02718

Re: K112891
Trade/Device Name: Apex Revision Knee System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer Semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH, MBH
Dated: February 13, 2012
Received: February 15, 2012

Dear Ms. Nassif:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number:

Device Name: Apex Revision Knee System

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112891